



Posted: 7/20/10 NF

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DIVISION OF PROFESSIONAL REGULATION

PUBLIC MEETING NOTICE:	BOARD OF PHARMACY
DATE AND TIME:	Wednesday, June 16, 2010 at 9:30 a.m.
PLACE:	Conference Room 1st floor, Cannon Building 861 Silver Lake Blvd., Dover, DE
APPROVED:	July 15, 2010

MEMBERS PRESENT

Sandra Robinson, R.Ph, Professional Member, President
Geoffrey N. Christ, Esq., R.Ph, Professional Member, Vice President
Howard Simon, R.Ph, Professional Member
Don Holst, R.Ph, Professional Member
Sebastian Hamilton, R.Ph, Professional Member
Joli Martini, R.Ph, Professional Member
Carolyn Calio, Public Member
David W. Dryden, R.Ph., J.D., Executive Secretary

MEMBERS ABSENT

David Bonar, Public Member

DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT

Allison Reardon, Deputy Attorney General
Nancy Fields, Administrative Specialist II
James Collins, Division Director

ALSO PRESENT

Lucy Somer
Sumera DeSilva
Judy Spica
Suzanne Raab-Long
Harini Pappu
Trent Beach
Ravi Pappu

CALL TO ORDER

Ms. Robinson called the meeting to order at 9:40 a.m.

REVIEW OF MINUTES

A motion was made by Mr. Hamilton, seconded by Mr. Simon to approve the May 19, 2010 minutes as presented. The motion unanimously carried.

PRESIDENT'S REPORT

Ms. Robinson attended a session of the House of Representatives on June 3, 2010 regarding HB 382. The bill passed the House to eliminate the word “licensed” in Statute 4740 of Title 16, which refers to pharmacy technicians.

Ms. Robinson was named as a member of the group for “Vaccination Strategies for Children – The Role of the Pharmacies” established by the Division of Public Health. There was a meeting on June 10, 2010 in Dover. Ms. Robinson stated that she had copies of the objectives of the meeting if any Board member would like to have one.

UNFINISHED BUSINESS

Legitimate Medical Purpose – Internet Pharmacy Proposal

This issue is tabled until the fall. At that time, the Committee will prepare a bill for the next Legislative session.

Drug Disposal and Distribution Review

A copy of the policies and procedures for drug disposal was distributed to the members. Another meeting will be scheduled for the near future.

Regulation 14 Review - Administration of Injectable Medications

Mr. Holst advised that a Committee meeting is scheduled for June 24, 2010 at 10:00 a.m. in Conference Room B. Ms. Robinson advised that she will take the information received from the Committee to the Division of Public Health meeting to share with them. They are attempting to come up with an acceptable solution and a wellness plan.

Prescription Monitoring Program (PMP)

Mr. Dryden reported that the bill passed the Senate and is ready for the floor in the House. The RFP, which is the bidding process for vendors, has been designed.

Regulation 7 Review

There was no report.

State of Emergency Issue Update

Mr. Dryden spoke to Tom Ellis and Jamie Turner at Homeland Security and DEMA and they advised him that a meeting was held regarding this issue. Mr. Collins will be making an inquiry about the meeting results. Some members of the Board expressed an interest in attending future meetings regarding this issue.

NEW BUSINESS

Pharmacist-In-Charge Interviews (PIC)

Mr. Simon conducted the PIC interviews for: Sumera DeSilva and Harini Pappu. Chaitanya K. Chittimalla was on the agenda, but not in attendance.

Pharmacist Licensure Ratifications

A motion was made by Mr. Christ, seconded by Mr. Holst, to ratify the applications that were issued by the Division of Professional Regulation for Nicole Srivastava, John E. Williams, Jr., Kingsley Ozioko, and Dheeraj Kumar Katangari. The motion unanimously carried.

Pharmacist Application Review

The Board reviewed and discussed the application for Ramakrishna Neravelta and decided that in order to make a decision to approve or not approve the application, additional information would be required.

A motion was made by Mr. Christ, seconded by Mr. Hamilton, to table the application for further clarification on the circumstances regarding the keys and the alarm code and why there were non-techs working in the Pharmacy. Ms. Martini and Mr. Holst opposed. The motion carried.

Consideration for Pharmacy and Pharmacist Emergency Suspension

Ms. Reardon stated that under Del. Code § 2519, the Board may order the suspension of a license to practice pharmacy prior to a hearing or simultaneously with the scheduling of a hearing if it finds that the licensee, by continuing in the practice of pharmacy, poses an imminent danger to public health, safety or welfare. The hearing must be held no later than 30 days from the date of service of the suspension order unless the hearing is continued at the request of the licensee.

Under Del. Code § 2530, the Board may suspend or revoke a permit to operate a pharmacy when examination or inspection of the pharmacy discloses that the pharmacy is not being operated according to law or is being operated in a manner which endangers public health, safety, or welfare. Del. Code § 2531 states: If the Board intends not to issue a permit or intends to suspend or revoke a permit, the Board shall give written notice to the applicant or permit holder of the intended action and the reasons thereof. The applicant or permit holder has at least 10 days from the date of notice to request a hearing.

The Board was presented with information regarding a complaint and hearing request from the State against Mr. Jeremy Kashuba and Renaissance Family Pharmacy.

Mr. Dryden stated that on June 14, 2010, Mr. Kashuba's Controlled Substance Registration was revoked and all the Controlled Substances were removed from the pharmacy.

Ms. Reardon advised the Board that she prepared the emergency suspension Order and asked that it be reviewed by the Board to see if any changes were necessary.

A motion was made by Mr. Hamilton, seconded by Mr. Christ, to put Renaissance Pharmacy and Mr. Kashuba on the agenda for July 15, 2010 in order to hold a hearing. Mr. Simon abstained. The motion carried.

A few minor changes were made to the Order.

A motion was made by Mr. Christ, seconded by Mr. Hamilton, to accept the terms of the suspension and the Board Order as written. Mr. Simon abstained. The motion carried.

The Order was signed by the Board. Mr. Dryden advised that he would hand deliver the Order today, making it effective today.

It was discussed that the PIC rules and transfer of controlled prescriptions rules do apply.

Election of Officers

Ms. Robinson stated that she enjoyed her time as the Board president, but it was time to give someone else an opportunity.

Mr. Simon nominated Mr. Hamilton for the position of president of the Board. Mr. Hamilton accepted the nomination. Ms. Calio seconded the nomination.

Mr. Holst nominated Mr. Christ for the president chair. Mr. Christ regretfully had to decline due to his increased time constraints and duties as town councilman.

No other members were nominated; therefore, Mr. Hamilton was elected the president/chair of the Board.

Mr. Hamilton nominated Mr. Simon for the position of vice president of the Board. Mr. Simon accepted the nomination. Mr. Holst seconded the nomination.

No other members were nominated; therefore, Mr. Simon was elected the vice president of the Board.

Congratulations and best wishes to Mr. Hamilton and Mr. Simon on their new positions.

Committee Reports

Joint Practice Committee – Don Holst and Howard Simon – No report.

Physician's Assistant Report – Sebastian Hamilton, R.Ph: - Mr. Hamilton reported that the council met on Tuesday, June 1, 2010. The council approved three new applications for licensure, nine applications for controlled prescriptive authority and non-controlled prescriptive authority. No applications were approved for only controlled prescriptive authority. The next meeting is scheduled for Tuesday, July 20, 2010.

Newsletter – Sandy Robinson, R. Ph., David Dryden, R.Ph., J.D, and Joli Martini, R. Ph.: The May issue of the newsletter was issued to the members. Mr. Dryden is preparing topics for future newsletters.

Legislative – Sandy Robinson, R.Ph, Howard Simon, R.Ph, Sebastian Hamilton, R.Ph, Don Holst, R.Ph, Geoffrey Christ, R.Ph., Esq., and David Dryden, R.Ph., J.D.: Ms Robinson reported that she spoke with Representative Carson. He advised her that the Delaware State Police had not discussed their concerns with him regarding the amendment; therefore, it was suggested that HB 235 be tabled and resubmitted into next legislative session if it was still desired. Ms. Robinson asked Ms. Reardon if the language that the Board has proposed could be put into Regulation 5 instead of the Statute. Ms. Reardon will review it and asked that it be put on the agenda for next meeting. HB477 was discussed with one change, line 13, to remove the word "pharmaceutical" to read "drug".

Continuing Education – Sandy Robinson, R. Ph., Geoffrey Christ, R.Ph., Esq., and Joli Martini, R. Ph.: No report.

Consumer Affairs – Carolyn Calio, and David Bonar: No report.

Professional Liaison – Sandra Robinson, R.Ph. and Joli Martini, R.Ph: Ms. Robinson stated that there will be a DSHP Summer Annual Meet & Greet tonight at the FireStone Roasting House at the Riverfront in Wilmington at 6:00 p.m.

The Delaware Public Health Preparedness Section is sponsoring three Bioterrorism Awareness and Strategic National Stockpile Training sessions. The first was on June 8th at Christiana Care, the second is on Tuesday, July 6, 2010 at Beebe's McCurry Conference Center in Rehoboth from 6 p.m. to 9 p.m. The third session is on August 10, 2010 from 9 a.m. to 12 p.m. at the Levin Center in Smyrna. It is being encouraged that at least one pharmacist and technician from every pharmacy attend one of the bioterrorism trainings. Pharmacists will receive 3 CE credits. Contact Kevin Musto, R. Ph.

MPJE Study Committee – Don Holst, R.Ph, Sebastian Hamilton, R.Ph, and James Kaminski: Mr. Kaminski reported that NABP suggested that the MPJE participating states review a small sub-set of items that they identified as potentially being affected by the new E-prescribing DEA rule which is anticipated to be implemented on June 1, 2010. This review was completed on May 26, 2010. He received an e-mail from Astrid Newcomb, Competency Assessment Items Coordinator NABP dated May 26, 2010 stating that four items will be removed from the Delaware pool if the changes go into effect June 1st.

Controlled Substance Liaisons – Geoffrey Christ, Howard Simon, and Dave Dryden: A Committee meeting is scheduled for May 26, 2010 to go over the topics at hand such as the PMP program, tamper-proof prescription pads, inspections and hearings. Mr. Christ stated that he and Ms. Davis-Oliva are working on clarifying language. Mr. Christ recently received a notification of a meeting with Homeland Security on June 23, 2010 regarding the tamper proof prescription pads. He will attend and report back to the Board.

Substantially Related Crimes Committee - Geoffrey Christ, Howard Simon, Allison Reardon, and Dave Dryden: Mr. Christ is compiling a list of issues for the next meeting.

Board Correspondence

There was no correspondence.

Inspection Report

When deficiencies are found during the inspection process or audits of controlled substances are not acceptable, the office requires written responses from the pharmacist-in-charge (PIC) or notifies the facility that a re-inspection will occur. There are four outstanding requests for a response at present. Four facilities are on hold for re-inspection.

Inspections of medical gas dispensers are still a priority for the office and are an ongoing process.

Effective Sunday, May 30, 2010, five Pathmark Pharmacies changed the pharmacy's Sunday hours of operation. The new hours will be 9am – 3pm.

After the March 17, 2010 Board meeting, lists of interim use medication submitted by Millennium Pharmacy Systems were reviewed. The group assigned felt the medications were too extensive and exceeded the requirements set forth in Regulation 11.3.2. In a letter dated June 3, 2010 (Received 6/4/2010) addressed to "Delaware State Board of Pharmacy" it was stated by Rushikesh Patel, R.Ph., PharmD, "each respective Long Term Care Facility will install a base 45 Med-dispense cart which shall stock no greater than sixty (60) medications for interim or

emergency use. The formulary for each site will be affix and readily available on each respective machine. Should you or the Board of Pharmacy need to review the formulary, I will be happy to provide a list for your reference.” Automation will need to be inspected when installed.

Other Business before the Board

There was no other business.

Public Comments

Mr. Collins recommended that the Controlled Substance Committee should consider having more Controlled Substance meetings due to the increase of complaints against licensees that have controlled substance registrations and inspections. He briefly spoke about some of the proposed bills in legislation right now and how the complaint process will be affected and improved. One bill, in particular, would allow the Division to withhold the names of the complainants. He stated that anonymous complaints don't work well with licensed practice issues because it is much more difficult to do a thorough investigation. This is just one of several bills in Legislation right now that could ultimately affect all licensees.

Mr. Christ again reiterated to Mr. Collins that the Division really needs to hire more pharmacy inspectors due to the increased diversion, theft, security and drug addiction issues that we are facing today. With only two inspectors, the inspections can only be done on openings and remodels right now, but routine inspections on hospitals, pharmacies, and distributors are desperately needed. He conducted research on the subjects and wrote a letter to Governor Minner last year about the issues that pharmacists and the citizens of Delaware were facing and made a few recommendations, one of which was the need for more inspectors.

Next Scheduled Meeting

The next meeting is scheduled for August 18, 2010; however, since the Board had an obligation to attend a disciplinary hearing on July 15, 2010, the Board decided to have a full meeting and to cancel the August meeting. This meeting will be held in Conference Room B at 9:30 a.m.

Adjournment

A motion was made by Mr. Hamilton, seconded by Mr. Christ to adjourn the meeting. The motion unanimously carried. The meeting adjourned at 11:53 a.m.

Respectfully submitted,



Nancy Fields
Administrative Specialist II